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(54) Auxiliary device for applying a vascular stent
over the balloon of a dilation catheter

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(57) An auxiliary device serves for applying a stent over the balloon of a dilation catheter. To that purpose it includes an intermediate sheath with an inner cavity that is conical in the longitudinal direction and locally substantially adapted to the cross section of the possibly partly deployed balloon as well as an outer wall with a conical development in the longitudinal direction similarly to the inner cavity. The cross section of the inner cavity is therefore locally marginally smaller than the net internal cross section of the undeformed stent.

DESCRIPTION

The invention relates to an auxiliary device for applying a vascular support (stent) over the balloon of a dilation catheter. In the following this object will be briefly designated auxiliary device.

Until today in vessel dilations (Angioplasties) it was common to re-use balloon catheters already used for the subsequent implantation of a stent. For that purpose, first of all vacuum is created in the balloon and the balloon is pressed/rolled together strictly by hand in order to let the stent slide over the balloon with as little resistance as possible when "mounting" the stent. Since the balloons have already been expanded once, this pressing together is not always easy and perfect. Consequently, small "plies" are frequently created on one side so that manual sliding of the stent with the fingers in the direction of the balloon "is hard to get". In order to avoid deforming the stent and perforating the balloon with the metal struts of the stent, the stent is slightly withdrawn and the balloon pressed together again. If mounting still fails to succeed, the process is once more repeated. If, irrespective of this, it fails again, finally a new, unused balloon is taken.

As a rule a stent slides better over an unused balloon. Frequently also a new stent must be used since the first stent was deformed during the mounting attempt.

After a bad mounting ("the stent lies too loose over the balloon") it happens that the stent is lost in the path to the target point in the guide catheter or in the vascular system. Consequently, as a rule the stent after being centered on the balloon is pressed firmly onto the balloon manually or with a special clamp. This correct adaptation is quite important in order to avoid skidding or even the loss of the stent. Mounting difficulties arise for about 10% of all stents. In about 1% this leads to the stent skidding or being deployment at a wrong place.

The object of the present invention is to provide an auxiliary device by means of which mounting the stent on the balloon of a dilation catheter is made simpler.

This object is achieved by means of the characterizing elements of claim 1.

With the help of this intermediate sheath a stent slid thereon can be caused to slide together with the intermediate sheath over the balloon without any problems.

The intermediate sheath with the stent at the narrower end is put on the balloon until the stent is located precisely in a centered position over the balloon. Thereafter the stent is retained manually and the intermediate sheath further drawn over the balloon so that the stent alone adheres onto the balloon.

In addition to *(leading to a)* significantly simpler mounting, with the intermediate sheath also narrower stents can be used that may be better adapted to the balloon surface, so that removal becomes unlikely.

An advantageous embodiment of the invention foresees that the intermediate sheath includes at its end with the larger cross section an appreciably rigid portion for pressing the balloon together when sliding over (the balloon) and that a flexible portion with a narrower cross section for inserting the stent thereon follows this rigid portion.

Thanks to the rigid portion, during sliding over the intermediate sheath, the balloon can be pressed together thereby sufficiently and the flexible portion and the stent located thereon can simultaneously expand when caused to slide thereover.

To advantage the intermediate sheath is comprised of a transparent material. In that way, the position of the stent over the balloon can be well controlled.

Further advantageous developments of the invention are recited in the subclaims.

The invention will now be described on the basis of the exemplary embodiments shown in the drawings. Therein:

- Figure 1 shows a longitudinal section of an auxiliary device,
- Figure 2 shows the auxiliary device with a dilation catheter with a shaft and a balloon portion with the stent,
- Figure 3 shows the arrangement of figure 2, wherein however the intermediate sheath was caused to slide further over the balloon,
- Figure 4 shows the insertion and sliding of the stent over the wire and the thinner portion of the intermediate sheath,
- Figure 5 shows the sliding and centering of the stent over the thinner portion of the intermediate sheath,
- Figure 6 shows the "withdrawal" of the intermediate sheath and
- Figure 7 shows the finally mounted stent.

The auxiliary device shown in the figures is essentially comprised of an intermediate sheath 1 that flares conically and exhibits round cross sections perpendicularly to the longitudinal direction. In its large portion 2 the wall of the intermediate sheath 1 can be more rigid, while in the narrow portion 3 it is flexible. A funnel-shaped flare 4 is present at the large end of the intermediate sheath.

Figure 2 shows the intermediate sheath 1 and the dilation catheter with its shaft 5 and the balloon portion 6. Before mounting the stent, a guide wire 8 is led through the inner cavity of the dilation catheter. The intermediate sheath 1 with the funnel-shaped portion 4 in advance is then inserted and caused to slide in the direction of the balloon 6 over this guide wire 8.

Figure 3 shows the large portion 2 of the intermediate sheath 1 sliding over the balloon 6. In that way the balloon, which is subject to vacuum, should be further pressed together. Specifically no plies must be flattened or arranged.

Figure 4 shows the insertion and the sliding of the stent 7 over the guide wire 8 and the thinner portion 3 of the intermediate sheath 1. The large

portion 2 of the intermediate sheath 1 is still located in the position over the balloon 6.

Figure 5 shows the sliding and centering of the stent 7 over the thinner portion 3 of the intermediate sheath 1 over the balloon 6. To that purpose the intermediate sheath 1 is drawn manually at the large portion 2 in the direction of the shaft 5. In this sliding step the stent 7 remains over the thinner portion 3 of the intermediate sheath 1.

Figure 6 shows the "withdrawal" of the intermediate sheath 1 in the direction of the catheter-shaft 5 for finally setting the stent 7 free. To that purpose the stent 7 is retained manually and the thinner portion 3 can slide as a result of being pulled at the large portion 2 between the stent 7 and the balloon 6.

Figure 7 shows the finally mounted stent 7. The intermediate sheath has slid extensively in the direction of the catheter-shaft 5, so that introduction of the stent in the vascular system is unimpeded.

CLAIMS

1. Auxiliary device for applying a stent over the balloon of a dilation catheter, **characterized in that** it includes an intermediate sheath (1) with an inner cavity that is conical in the longitudinal direction and locally substantially adapted to the cross section of the possibly partly deployed balloon (6) as well as an outer wall with a conical development in the longitudinal direction similarly to the inner cavity, whose cross section is locally marginally smaller than the net internal cross section of the undeformed stent (7).

2. Auxiliary device according to claim 1 characterized in that the intermediate sheath (1) at its end (2) with the large cross section exhibits a substantially rigid portion for pressing the balloon (6) together upon sliding over and that to this rigid portion follows a flexible portion (3) having a narrower cross section for inserting the stent (7).

3. Auxiliary device according to claim 1 or 2, characterized in that the rigid portion and the flexible portion of the intermediate sheath (1) are preferably comprised of the same material and that the wall thickness in the rigid portion is larger than in the flexible portion.

4. Auxiliary device according to any of claims 1 to 3, characterized in that the intermediate sheath (1) is comprised of a transparent material.

5. Auxiliary device according to any of claims 1 to 4, characterized in that at the insertion end of the intermediate sheath (1) there is provided a funnel-shaped enlarged portion (4).

6. Auxiliary device according to any of claims 1 to 5, characterized in that the outer portion of the intermediate sheath (1) up to the enlarged portion (4) possibly provided at the insertion end and preferably also in its inner cavity extends continuously conically throughout.

(2 pages drawing).